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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,432	04/13/2004	Scott Phillip Baron	PC18327A	5027

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EXAMINER	
HIRIYANNA, KELAGINAMANE T	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,432	BARON ET AL.	
	Examiner	Art Unit	
	Kelaginamane T. Hiriyanna	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1 drawn to a genetically modified, non-human mammal comprising an α2/δ1 gene comprising 290-like mutation, classified in class 800, subclass 8.

II. Claim 2-9 drawn to a genetically modified, non-human mammal wherein the modification results in a mutated α2/δ2 gene encoding polypeptide, classified in class 800, subclass 8.

III. Claims 10, 11, 13-4, and 17-23 drawn to a isolated nucleic acid molecule and to a host cell comprising mutated α2/δ2 gene encoding polypeptide, classified in class 435, subclass 320.1 and subclass 325.

IV. Claim 12 drawn to a genetically modified, non-human mammal comprising nucleic acid sequence set forth in SEQ ID NO: 39, classified in class 800, subclass 8.

V. Claim 15-16 drawn to a non-human mammal that is the progeny of a first and as second mammal wherein the first mammal is a genetically modified with mutation in α2/δ2 gene and the second mammal is a genetically modified with mutation in α2/δ1 gene classified in class 800, subclass 8.

VI. Claims 24-25 drawn to a method of identifying a gene that demonstrates modified expression profile in a cell with mutated α2/δ2 gene, classified in class 435, subclass 375.

VII. Claims 26-27 drawn to a method of identifying a protein that demonstrates modified proteomic and/or post translational profile in a cell with mutated α2/δ2 gene, classified in class 435, subclass 7.1.

VIII. Claims 28-29 drawn to a method of producing a transgenic animal, classified in class 800, subclass 21.

IX. Claims 30-40 drawn to a method of determining the physiological effect of compounds involving binding to α2/δ2 polypeptide, classified in class 800, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention I transgenic animals comprise a mutant a transgene of α2/δ1 gene whereas invention II transgenic animals comprise a mutant transgene of α2/δ2 gene. The gene and the gene products of invention I and II are thus structurally and genetically different entities. Mutant gene in transgenic animal of invention IV and various combinations of mutant genes in of invention V contribute differently and distinctly to their genotypes and phenotypes and hence are effectively different and distinct from each other and the transgenic animals of inventions I and II. Therefore, a search and examination for the patentability of the said inventive groups are not co-extensive and would generate an undue burden on the examiner. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions III is unrelated to inventions I-II, and IV-V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions III comprises nucleic acids and cultured cells with transgene. The nucleic acids of invention III are operationally distinct inventions of Groups I-II, IV and V involving live transgenic non-human animals. Further the inventions in Group I-II, IV and V are come under statutorily different classification than group II and V. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions of Groups I-II, and IV-V are related to inventions of group VI-IX as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The processes of use in inventions VI-IX can be practiced with products of either of the groups. Further, the transgenic animals of different inventions above can be used in for carrying out either of the distinct and different methods described by inventions VI-IX. Therefore, a search and examination for the patentability of the said distinct inventive groups generate an undue burden on the examiner. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A further group restriction is required for inventive groups II and V as they each involve multiple and distinct transgenic animal genotypes. The different mutations of the transgenes and their different combinations generate structurally different polypeptides in the transgenic animal and lead to distinctive genotypes and phenotypes.

Should Group II be selected a further group restriction is required as follows as each of the transgenic animal with mutation combination of α2/δ2/ are distinct and different genetic entities. A search examination together is burdensome. Hence the restriction is proper:

II(i) Claim 2-9 drawn to (a-c) a genetically modified, non-human mammal wherein the modification results in a mutated α2/δ2 gene encoding polypeptide comprising arginine to non-arginine substitution or arginine to aliphatic aminoacid substitution or arginine to alanine substitution one of two flanking arginines in RRR motif.

II(ii) Claim 2-8 drawn to (d) a genetically modified, non-human mammal wherein the modification results in a mutated

α2/δ2 gene encoding polypeptide comprising a deletion in atleast one of flanking arginines in RRR motif.

II(iii) Claim 2-8 drawn to (e) a genetically modified, non-human mammal wherein the modification results in a mutated α2/δ2 gene encoding polypeptide comprising a deletion up to 9 residues N terminal to RRR motif and up to 5 residues C terminal to RRR motif.

II(iv) Claim 2-8 drawn to (f) a genetically modified, non-human mammal wherein the modification results in a mutated α2/δ2 gene encoding polypeptide comprising a deletion up to 9 residues N terminal to RRR motif and at least one of flanking arginines in RRR motif.

II(v) Claim 2-8 drawn to (g) a genetically modified, non-human mammal wherein the modification results in a mutated α2/δ2 gene encoding polypeptide comprising a deletion up to 5 residues C terminal to RRR motif and at least one of flanking arginines in RRR motif.

Should Group VI be selected a further group restriction is required as follows as each of the double transgenic combination (represented in parenthesis) of first mammal//second mammal (or α2/δ2//α2/δ1) are distinct and different genetic entities. A search examination together is burdensome. Hence the restriction is proper:

V(i) Claim 15-16 drawn to double transgenic (claim 2 a-c// claim 15 a-c) genetically modified, non-human mammal progeny of first mammal wherein the modification results in a mutated α2/δ2 gene encoding polypeptide comprising arginine to non-arginine substitution or arginine to aliphatic aminoacid substitution or arginine to alanine substitution one of two flanking arginines in RRR motif and a second mammal mutated α2/δ1 gene encoding polypeptide comprising arginine to non-arginine

substitution or arginine to aliphatic aminoacid substitution or arginine to alanine substitution one of two flanking arginines in RRR motif

And similarly the combination of first and (//) second mammal in the following groups as follows:

V(ii) drawn to (claim 2 a-c// claim 15 d).

V(iii) drawn to (claim 2 a-c// claim 15 e)

V(iv) drawn to (claim 2 a-c// claim 15 f)

V(v) drawn to (claim 2 a-c// claim 15 g)

V(vi) Claim 15-16 drawn to (claim 2 d// claim 15 a-c) a genetically modified, non-human mammal wherein the modification results in a mutated α2/δ2 gene encoding polypeptide comprising a deletion in atleast one of flanking arginines in RRR motif and a second mammal mutated α2/δ1 gene encoding polypeptide comprising arginine to non-arginine substitution or arginine to aliphatic aminoacid substitution or arginine to alanine substitution one of two flanking arginines in RRR motif.

And similarly following groups:

V(vii) drawn to (claim 2 d// claim 15 d).

V(viii) drawn to (claim 2 d// claim 15 e)

V(ix) drawn to (claim 2 d// claim 15 f)

V(x) drawn to (claim 2 d/ claim 15 g).

V(xi) Claim 15-16 drawn to (claim 2 e// claim 15 a-c) a genetically modified, non-human mammal wherein the modification results in a mutated α2/δ2 gene encoding polypeptide comprising a deletion up to 9 residues N terminal to RRR motif and up to 5 residues C terminal to RRR motif and a second mammal mutated α2/δ1 gene encoding polypeptide comprising arginine to non-arginine substitution or arginine to aliphatic aminoacid substitution or

arginine to alanine substitution one of two flanking arginines in RRR motif.

And similarly the following groups:

V(xii) drawn to (claim 2 e// claim 15 d).

V(xiii) drawn to (claim 2 e// claim 15 e)

V(xiv) drawn to (claim 2 e// claim 15 f)

V(xv) drawn to (claim 2 e// claim 15 g)

V(xvi) Claim 15-16 drawn to (claim 2 f// claim 15 a-c) a genetically modified, non-human mammal wherein the modification results in a mutated α2/δ2 gene encoding polypeptide comprising a deletion up to 9 residues N terminal to RRR motif and at least one of flanking arginines in RRR motif and a second mammal mutated α2/δ1 gene encoding polypeptide comprising arginine to non-arginine substitution or arginine to aliphatic aminoacid substitution or arginine to alanine substitution one of two flanking arginines in RRR motif.

And similarly the following groups:

V(xvii) drawn to (claim 2 f// claim 15 d).

V(xviii) drawn to (claim 2 f// claim 15 e)

V(xviv) drawn to (claim 2 f// claim 15 f)

V(xx) drawn to (claim 2 f// claim 15 g)

V(xxi) Claim 15-16 drawn to (claim 2 g// claim 15 a-c) a genetically modified, non-human mammal wherein the modification results in a mutated α2/δ2 gene encoding polypeptide comprising a deletion up to 5 residues C terminal to RRR motif and at least one of flanking arginines in RRR motif and a second mammal mutated α2//δ1 gene encoding polypeptide comprising arginine to non-arginine substitution or arginine to aliphatic aminoacid substitution or

arginine to alanine substitution one of two flanking arginines in RRR motif.

And similarly the following groups:

V(xxii) drawn to (claim 2 f// claim 15 d).

V(xxiii) drawn to (claim 2 f// claim 15 e)

V(xxiv) drawn to (claim 2 f// claim 15 f)

V(xxv) drawn to (claim 2 f// claim 15 g).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The claims in this application require further species restriction under 35 U.S.C. 121 as follows:

(a). Applicant is required chose a single corresponding species polypeptide SEQ ID NO. among the recited in claim 4 i.e., SEQ ID NO: 32 or 33 or 34 or 35 or 36.

(b). Applicant is required choose a single species of activity or disorder among the recited in claim 29 as well as claim 31, 37 and 39 i.e., pain or hyperalgesia or anxiety or sedation or epilepsy or convulsion.

(c). Applicant is required to choose single species procdures among the recited in claim 40 i.e., α2/δ1 ligand binding or gabapentin binding or formalin food-pad procedure or tail suspension test or maximal electroshock or Vogel procedure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the claims 1-3, 6, 8-14, 16-17, 20, 22, 28, 32, 36, 48 are generic:

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna* whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Friday from 9 AM-5PM. Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst *William N. Phillips*, whose telephone number is **(571) 272-0548.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Dave Nguyen*, may be reached at **(571) 272-0731.** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

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Art Unit 1633

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